DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2015

Alma Lasers Incorporated
% Ms. Kathy Maynor
USA Regulatory
26 Rebecca Court
Homosassa, Florida 34446

Re: K141237
Trade/Device Name: Alma Harmony Lite
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF, ILY
Dated: February 4, 2015
Received: February 6, 2015

Dear Ms. Maynor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141237

Device Name
Alma Harmony Lite

Indications for Use *(Describe)*

Indications for Use :

The Harmony Lite is intended for use in aesthetic, cosmetic, and surgical applications requiring the ablation, vaporization, excision, incision, and photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialties of dermatology, general and plastic surgery, and aesthetic applications, as follows:

500-600 nm Dye VL Pro Module AFT Hand piece

The Advanced Fluorescence Technology (AFT) Dye VL Pro Module handpiece (with and without contact-cooling) is indicated for:

•The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and legtelangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

• For use on Fitzpatrick skin types I-V.

540-950 nm VP PRO AFT Hand piece

The Advanced Fluorescence Technology (AFT) VP ProModule handpieces (with and without contact-cooling) are indicated for:

•The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles),lentigines, nevi, melasma, and cafe-au-lait macules.

•The treatment of cutaneous lesions including warts, scars and striae.

•The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and legtelangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

• Use on all skin types (Fitzpatrick I-VI).

570-950 nm SSR Pro Module AFT Hand piece

The Advanced Fluorescence Technology (AFT) 570-950 nm SSR Module handpiece (with and without contact-cooling) is indicated for:

•The treatment of benign pigmented epidermal lesions, including dyschromia , hyperpigmentation, melasma and ephelides (freckles).

•The treatment of face and body vascular and pigmented lesions.

•The treatment of cutaneous lesions, including scars and striae.

• The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias,rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

•Use on all skin types (Fitzpatrick I-VI).

590 nm LED Module Handpiece

The 590 nm LED module handpiece is indicated to:

• Provide topical heating to promote increased blood flow for temporary relaxation of muscle and relief of pain .

• Provide topical heating for the purpose of elevating and/or maintaining tissue temperature.

780-950 nm SHR PRO AFT Module Hand piece

The Advanced Fluorescence Technology (AFT) 780-950 nm SHR PRO (with and without contactcooling) is indicated for:

•The treatment of pseudofolliculitis barbae (PFB).

•The removal of unwanted hair and to effect stable long-term or permanent hair reduction. Permanent reduction in hairregrowth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12months after the completion of the treatment regime.

NIR Large and Small Modules :
The NIR Modules are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscle back pain.

Thermoelectric Cooler (TEC)
The thermoelectric cooler, integrated into the light and laser handpieces, is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to:
• Reduce pain during and/or associated with light or laser treatment;
• Reduce discomfort during and/or associated with light or laser treatment;
•Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during. and/or associated with light orlaser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation;
• Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular orpigmented lesions); and
• Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 8 – 510(k) Summary or 510(k) Statement

I. General Information

Submitter: Alma Lasers Inc.
485 Half Day Rd. Suite 100
Buffalo Grove, IL 60089

Contact Person: Avi Farbstein
General Manager, EVP
Alma Lasers Inc.

Kathy Maynor
USA Regulatory
Alma Lasers Inc.

Summary Preparation Date: March 12, 2015

II. Names

Device Names: Harmony Lite Multi-Application Platform

Primary Classification Names: Surgical Powered Light Instrument, Ultraviolet Dermatological Light, and LED Phototherapy device

III. Predicate Devices

- K072564 Alma Harmony XL Plarform
- K140009 The Modified Alma Lasers Soprano XL Family of Multi-Application and Multi-Technology Platforms

IV. Product Description

The Alma Lasers Harmony Lite Multi-Application Platform is comprised of the following main components:

- The main console unit that incorporates the touch-screen control panel, power supply modules, cooling system, switching module, service panel and isolating transformer.
- Variety of handpieces, including IPL, LED and NIR modules
- Footswitch.

V. Indications for Use

The Alma Lasers Harmony Lite Multi-Application Platform is intended for use in dermatologic and general surgical procedures.

The Indications for Use of the Harmony Lite Multi-Application Platform are provided in the tables below.

VI. Summary of Technical Characteristics

	Dye VL Pro IPL Handpiece – this submission	**K072564 – Alma** **VL515 IPL handpiece** **Primary Predicate**
Characteristic		
Wavelength (nm)	**500-600nm**	**VL515 Handpiece (515nm-950nm)**
Intended Use	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology
Indications for Use	Indicated for the treatment of: • Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea,, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations • For Use on skin types (I-V)	Indicated for the treatment of: • Moderate inflammatory acne (acne vulgaris) • Tattoos and benign pigmented epidermal and cutaneous lesions including warts, scars ,striae; dyschromia, hyperpigmentation, melasma, epithelides (freckles), lentigines, nevi, and café-au-lait macules • Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations • For use on skin types (I-V)
Pulse Width (msec)	10,12,15	10, 12, 15
Pulse Repetition Rate (Hz)	2/3	2/3
Energy Density (Fluence) (J/cm^2)	10-30	10-30
Spot Size (mm)	3 cm^2	3 cm^2

	VP PRO – this submission	**Previously Cleared K072564 – Alma IPL handpiece VL/PL, VP and SSR** **Primary Predicate**
Characteristic		
Wavelength	**540-950nm**	**540-950nm**
Intended Use	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology
Indications for Use	Indicated for the treatment of: • The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and cafe-au-lait macules. • The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • Use on all skin types (Fitzpatrick I-VI).	• The treatment of moderate inflammatory acne vulgaris. · • The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and caf6-au-lait macules. • The treatment of cutaneous lesions including warts, scars and striae. · • The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • The removal of unwanted hair to effect stable long-term or permanent hair reduction. • Use on all skin types (Fitzpatrick I-VI).
Energy Density (Fluence) (J/cm^2)	10-30	10-30
Pulse Repetition Rate (Hz)	2/3	2/3
Pulse Width (msec)	10, 12, 15	10, 12, 15
Spot size	3 cm^2	3 cm^2

	This submission – SSR IPL handpiece	**K072564 – Alma** **SR IPL handpiece** **Primary Predicate**
Characteristic		
Wavelength (nm)	**570-950**	**570-950**
Intended Use	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology
Indications for Use	The Advanced Fluorescence Technology (AFT) 570-950 nm SSR Module handpiece (with and without contact-cooling) is indicated for: • The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles). • The treatment of face and body vascular and pigmented lesions. • The treatment of cutaneous lesions, including scars and striae. • The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • Use on all skin types (Fitzpatrick I-VI).	The Advanced Fluorescence Technology (AFT) 570-950 nm SR Module handpiece (with and without contact-cooling) is indicated for: • The treatment of moderate inflammatory acne vulgaris. • The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles). • The treatment of face and body vascular and pigmented lesions. • The treatment of cutaneous lesions, including scars and striae. • The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • The removal of unwanted hair to effect stable long-term or permanent hair reduction. • Use on all skin types (Fitzpatrick I-VI).
Energy Density (Fluence) (J/cm^2)	10-25 J/cm^2	10-25 J/cm^2
Pulse Repetition Rate (Hz)	2/3	2/3
Pulse Width (msec)	10,12,15 msec	10, 12, 15 msec
Spot size (mm)	3 cm^2	3, 6 cm^2

	This submission **SHR IPL handpiece**	**Previously Cleared K072564 - Alma SHR IPL** **Primary Predicate**
Characteristic		
Wavelength (nm)	**780-950**	**780-950**
Intended Use	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology
Indications for Use	The Advanced Fluorescence Technology (AFT) 780-950 rnm SHR Module handpiece (with and without contact-cooling) is indicated for: • Removal of unwanted hair Effect stable or permanent hair reduction. Permanent reduction in hair regrowth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime • The treatment of pseudofolliculitis barbae (PFB). • Use on all skin types (Fitzpatrick I-VI), including tanned skin	The Advanced Fluorescence Technology (AFT) 780-950 rnm SHR handpieces (with and without contact-cooling) is indicated for: • The treatment of pseudofolliculitis barbae (PFB). • The removal of unwanted hair and to effect stable long-term or permnanent hair reduction. • Use on all skin types (Fitzpatrick I-VI), including tanned skin.
Pulse Width (msec)	30,40,50 msec	30,40,50 msec
Pulse Repetition Rate (Hz)	4	4
Energy Density (Fluence)	1-5 J/cm2 for SHR 5-25J/cm^2 for HR	1-5 J/cm2 for SHR 5-25J/cm^2 for HR
Spot Size (mm)	3 cm^2	3 cm^2

	LED Handpiece – No modifications – this submission	**Previously Cleared K072564 Alma Lasers LED Handpiece** **Primary Predicate**
Characteristic		
Intended Use	Intended for use in dermatologic procedures	Intended for use in dermatologic procedures
Indications for Use	The 590 nm LED module handpiece is indicated to: · • Provide topical heating to promote increased blood flow for temporary relaxation of muscle and relief of pain. • Provide topical heating for the purpose of elevating and/or maintaining tissue temperature.	The 590 nm LED module handpiece is indicated to: · • Provide topical heating to promote increased blood flow for temporary relaxation of muscle and relief of pain. • Provide topical heating for the purpose of elevating and/or maintaining tissue temperature.
Wavelength (nm)	590 (amber)	590 (amber)
Output power (mW)	1,800	1,800
Treatment Area	0.9 cm^2 (0.14 sq.in.)	0.9 cm^2 (0.14 sq.in.)
Mode	Pulsed/Continuous Wave (CW)	Pulsed/Continuous Wave (CW)

	This submission Alma Lasers NIR Large Module	K140009 Alma Lasers NIR Module
		Primary Predicate
Parameter		
Product Code & Regulation No.	ILY 21CFR 890.5500	ILY 21 CFR 890.5500
Wavelength [nm]	1300	1300
Lamp Type	Quartz Tube	Quartz tube
Intended Use	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature
Indications for Use	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.
Power Control	Time control	Time control
Mode	Pulsed	Pulsed
Fluence [J/cm^2]	0.55-5.5	0.55-5.5
Pulse Width [sec]	1-5	1 - 5
Spot Size [mm*mm] or cm^2]	18	18
Cooling	Contact cooling Thermo-electric (TEC)	Contact cooling Thermo-electric (TEC)
Treatment Mode	In-motion	In-motion
Exposure Indicator	Audible & visual indicator	Audible & visual indicator
How Supplied	Non-sterile, cleanable	Non-sterile, cleanable
Module Dimensions	190*80*56mm (L*W*H)	190*80*56mm (L*W*H)

Parameter	This submission Alma Lasers NIR Small Module	K140009 Alma Lasers NIR Module **Primary Predicate**
Product Code & Regulation No.	ILY 21 CFR 890.5500	ILY 21 CFR 890.5500
Wavelength [nm]	1300	1300
Lamp Type	Quartz tube	Quartz tube
Intended Use	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature	Intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature
Indications for Use	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	For the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.
Power Control	Time control	Time control
Mode	Pulsed	Pulsed
Fluence [J/cm²]	.55-5.5	5.5
Pulse Width [sec]	1-5	1 - 5
Spot Size [mm*mm] or [cm^2]	6.4	6.4
Cooling	Contact cooling Thermo-electric (TEC)	Contact cooling Thermo-electric (TEC)
Treatment Mode	In-motion	In-motion
Exposure Indicator	Audible & visual indicator	Audible & visual indicator
How Supplied	Non-sterile, cleanable	Non-sterile, cleanable

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Alma Lasers Harmony Lite Multi-Application Platform is substantially equivalent to the predicate devices. Additional safety testing was performed as discussed in section 18 of the submission.

The Alma Harmony Lite was tested by a certified laboratory in accordance with:

IEC 60601-1:2005 + Corr.1 (2006) + Corr. 2 (2007) Medical Electrical Equipment: Part 1 General Requirements for Basic Safety and Essential Performance

IEC60601-1-2: 2007 Medical electrical equipment: Part 1-2; Collateral Standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-2-57: 2011 1st edition" Medical electrical equipment: Part 2: Particular requirements for the basis safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

The software was documented, verified and validated (test reports in submission) in accordance with IEC 62304:2006 – Medical Device Software: Software Life Cycle Processes and ISO 14971:2012 – Medical Devices: Application of Risk Management to Medical Devices.

VIII. Animal Data

Collateral animal data was presented on a pig study performed at the University of California for the Dye VL Pro handpiece. We compared the results from our IPL experiments to acquired pulsed dye laser (PDL) data from a previous study and determined that IPL treatments can also produce persistent vascular shutdown. We ran Monte Carlo simulations to investigate the relationship between absorbed energy, wavelength, and penetration depth. The data collectively demonstrate the potential to achieve removal of vascular lesions using the IPL.

IX. Conclusion

The Alma Lasers Harmony Lite Multi-Application Platform was found to be substantially equivalent to the predicate devices.

The Alma Lasers Harmony Lite Multi-Application Platform shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate devices.